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DATE MAILED: 06/15/2006

APPLICATION NO.	NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/648,811	08/25/2003		Paul A. Price	407T-895413US	5266	
22798	7590	06/15/2006		EXAMINER		
•		JAL PROPERT	NGUYEN, BAO THUY L			
P O BOX 45 ALAMEDA,				ART UNIT	PAPER NUMBER	
				1641		

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	<u> </u>					
		10/648,811	PRICE ET AL.	PRICE ET AL.					
	Office Action Summary	Examiner	Art Unit						
		Bao-Thuy L. Nguyen	1641						
Period f	The MAILING DATE of this communication apports or Reply	pears on the cover sheet w	ith the correspondence ac	ddress `					
WHI0 - Exte after - If NO - Failt Any	IORTENED STATUTORY PERIOD FOR REPL CHEVER IS LONGER, FROM THE MAILING D resions of time may be available under the provisions of 37 CFR 1.1 resix (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period ure to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing led patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNI (36(a). In no event, however, may a will apply and will expire SIX (6) MOI e, cause the application to become A	CATION. reply be timely filed NTHS from the mailing date of this of BANDONED (35 U.S.C. § 133).						
Status			:	•					
1)⊠	Responsive to communication(s) filed on 25 A	lugust 2003.							
2a)□	<u> </u>	s action is non-final.							
3)□	Since this application is in condition for allowa	nce except for formal mat	ters, prosecution as to th	e merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.									
D:i4	in a of Olaima			:					
Disposit	ion of Claims								
4)⊠	Claim(s) <u>1-4</u> is/are pending in the application.								
_	4a) Of the above claim(s) is/are withdra	wn from consideration.							
5)	Claim(s) is/are allowed.								
6)⊠	Claim(s) <u>1-4</u> is/are rejected.								
7)	Claim(s) is/are objected to.								
8)□	Claim(s) are subject to restriction and/o	or election requirement.		. : :					
Applicat	ion Papers			:					
9)[The specification is objected to by the Examine	er.							
•	The drawing(s) filed on is/are: a) acc		by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
	Replacement drawing sheet(s) including the correct			FR 1.121(d).					
11)	The oath or declaration is objected to by the Ex	xaminer. Note the attache	d Office Action or form P	TO-152.					
Dui a vita .	don 25 U.S.O. S.440								
	under 35 U.S.C. § 119								
	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C.	§ 119(a)-(d) or (f).						
a)	☐ All b)☐ Some * c)☐ None of:								
	1. Certified copies of the priority document								
	2. Certified copies of the priority document								
	3. Copies of the certified copies of the prior		received in this National	l Stage					
	application from the International Burea								
* (See the attached detailed Office action for a list	of the certified copies not	received.	: . !					
A44.a.b	4/5)								
Attachmer 1) Notice	រេ(s) ce of References Cited (PTO-892)	4\ \ Interview	Summary (PTO-413)						
	ce of Draftsperson's Patent Drawing Review (PTO-948)	Paper No	(s)/Mail Date	: :					
3) 🔯 Infor	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	·	Informal Patent Application (PT	O-152)					
Pape	er No(s)/Mail Date	6) 🔲 Other:	_						

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DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1 and 3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed antibody is not recited as being an isolated product.

It is recommended that the claim be amended as follows:

Claim 1. An <u>isolated</u> antibody that specifically binds YKL-40.

Claim Rejections - 35 USC § 102

- 3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
 - (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

A person shall be entitled to a patent unless -

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Johansen et al (Abstract for Scientific Conference. Davos, Switzerland. Published on or after July 12, 1992) in light of Johansen et al (British Journal of Rheumatology. 1993. Vol. 32, No. 11, pages 949-955).

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The Johansen abstract discusses the discovery of YKL-40 and specific radioimmunoassay for the same. The abstract did not list the reagents of the radioimmunoassay. However, in a post filing date reference, Johansen discusses the specific reagents that are necessary for a radioimmunoassay of YKL-40, including a polyclonal antibody that binds specifically thereto. See page 950.

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen (in light of Johansen) in view of Maurer et al (Methods in Enzymology. Vol. 70, pages 49-70. 1980).

See the discussion of Johansen above. Johansen differs from the instant claims in failing to teach a monoclonal antibody specific for YKL-40.

Maurer, however, discloses methods of making polyclonal and monoclonal antibodies to many different antigens and

Therefore, one of ordinary skill in the art would have had an extremely reasonable expectation of success in producing a monoclonal antibody to the YKL-40 of Johansen

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using the method taught by Maurer because the use of a monoclonal antibody to YKL-40 is of unquestioned research and interest and one of ordinary skill in the art would have had a reasonable expectation of success at generating monoclonal antibodies reactive with YKL-40 due to the teachings that this protein is immunogenic and that immunization of mice or other laboratory animals with various immunogenic YKL-40 antigens, in conjunction with notoriously old and well known fusion techniques, achieves the expected result, i.e. the production of monoclonal antibodies reactive with said YKL-40 antigens.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen (in light of Johansen) in view of Olsen et al (WO 90/08195).

See the discussion of Johansen above. This reference differs from the instant claim in failing to teach a labeled antibody.

Olsen discloses labeled monoclonal antibodies to human Type IX collagen and human c(IX) collagen chains. Olsen teaches that monoclonal antibodies can be labeled by any conventional procedure with any suitable label and employed in a conventional assay procedure such as ELISA and radioimmunoassay. See page 7, lines 14-24.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to label the antibody of Johansen such as taught by Olsen because labeling techniques are disclosed as well known and conventional in the art.

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Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic. Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen Primary Examiner

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